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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/815,262	03/21/2001	Charles Q. Meng	04676.105051 (ATH114US)	4560

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KING & SPALDING
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ATLANTA, GA 30303-1763

EXAMINER

VOLLANO, JEAN F

ART UNIT	PAPER NUMBER
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1621

12

DATE MAILED: 05/27/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/815,262

Applicant(s)

MENG ET AL.

Examiner

Jean F. Vollano

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23,28-38,40-42,44-50,52-54,56-58,60-62,64-66,68-70 and 72-76 is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1,2,6,14,15,28 and 72-76 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

Continuation of Disposition of Claims: Claims withdrawn from consideration are 3-5,7-13,15-23,29-38,40-42,44-50,52-54,56-58,60-62,64-66 and 68-70.

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DETAILED ACTION

1. The amendment filed 1/6/2003 has been entered. Claims 1-23, 29-38, 40-42, 44-50, 51-54, 56-58, 60-62, 64-66, and 68-70 are pending. According to the restriction written by Examiner Lewis claims 1-23 and 29-35 are elected and therefore claims 36-38, 40-42, 44-50, 51-54, 56-58, 60-62, 64-66 and 68-70 fall in the category of non elected subject matter.

There are many problems with restriction. First of all the compounds of claims 1-23 and 28-35 are not found in one class as the examiner has written in the restriction requirement. Secondly the election of species is not drawn to any of the Z groups but only to four groups which does not give the applicant a choice of any Z group which is a non carbohydrate . There are Z groups which have terminal carboxylic acids such as those being claimed in 09/370046 cited on the 1449 which is now a patent and Z groups which have terminal carboxylic esters which is claimed in US Ser No 09/570098 now pending. It is assumed that since the copending applications have these Z groups they were not added to the Z groups or requested by applicant to be added. However the sulfur acid is also being claimed in US Ser No. 09/833407. Also a species has not been elected. A species is a particular compounds with all the variables defined. Finally the way the restriction has been conducted it appears that applicant in choosing the non carbohydrates assumes that all the non carbohydrate Z will be searched. The various Z's fall in different classes and subclasses and are patentable distinct and there is a burdensome search for

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the various Z structures. This heterocycles for example are found in classes 540, 546, 544, 548 and 549. These are classes that are not searched by the art unit that this case was transferred to.

The case was transferred to Art Unit 1621 since the Z structure chosen was an alcohol and that election gives the class 568 with the various subclasses of the alcohol and sulfide. The Phosphorous acid is found in the class 562 under phosphorus acid subclasses. The sulfur acid is found in class 562 under sulfur acid subclasses. The ester is found in class 560 under various subclasses depending on the functional groups on the acid side and the functional groups on the alcohol side that make up the ester. The class and subclass for carboxylic acids is 562 wherein there is not phosphorus or sulfur acids present. Indeed the classes and subclasses in group I in themselves are burdensome. The examiner was going to re-write the restriction to Group I to break them down into their patentable distinct classes and subclasses. However since the case has just been given to the examiner and the election was sent in January, the examiner will examine the subgenus elected (there was not a species elected), with the tertbutyl group being the other R groups as in the dependent claims, to hasten prosecution. However it is noted that the examiner can at any time rewrite the restriction. The examiner could rewrite the restriction to limit the classes to one group selected from Z being carboxylic acids , carboxylic esters , amine compounds (those are found in class 564), alcohols including polyhydroxylated , terminal phosphorus acids, terminal sulfur acids as well as terminal heterocycles which will further broken down by structure (i.e. all nitrogen containing, nitrogen and sulfur containing etc which all have different classes and subclasses) and of course terminal sugars and carbohydrates. These

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functional groups determine the class and subclass and if one group is found as is given below in the art rejection then that compound does not obviate a rejection over the other compounds and they are therefore patentably distinct and there is a burdensome search. If applicant would like to discuss the possibilities of ways to proceed then please call the examiner. For now the search will be directed to hydroxides and polyhydroxides as elected.

The examiner has searched the elected compound. Since the other Rs in the structure were not defined the examiner assumes that the chosen R groups are the tert butyl groups found in one of the claims applicant states contains the elected species. The elected material for the OH is found in claims 1, 2, 6, 14, 15, 28, 72, 73, 74, 75, 76 and for the present these will be the claims examined. Upon finding a rejection of this species all other claims will be considered non elected for the present.

2. This application claims benefit of 60/191,046 in the information data sheet. There are no claims under 35 U.S.C. 120 and/or 121 on the bibliographic data sheet. There is claim to priority in the oath/declaration. Therefore there seems to be a problem with the bib sheet and that will be addressed as soon as the following problems have been cleared up. Applicant has stated in the first sentence of the specification there is a claim to priority of 09/370,046 filed 4/6/1999 and 09/079,213 filed May 14, 1998. However there is no listing of what relationship these applications have to the instant application. Are they supposed continuations or are they CIPs or divisionals etc? Upon review it appears that the instant invention contains material not found in

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the two priority documents listed. The examiner did a word search of the patents that came from 09/370,046 and 09/079,213 and did not find the word, glucose or mannose or threose or heterocycle or disaccharide in either of the priority documents. MPEP 201.07 gives the definition of a Continuation Application.

“A continuation is a second application for the same invention claimed in a prior >nonprovisional< application and filed before the original becomes abandoned or patented. The continuation application may be filed under 37 CFR 1.53>(b)(1)<, 37 CFR 1.60, or 37 CFR 1.62. The applicant in the *>continuation< application must include at least one inventor named in the prior >nonprovisional< application. **The disclosure presented in the continuation must be the same as that of the original application;** i.e., the continuation should not include anything which would constitute new matter if inserted in the original application.”

Note that the disclosure in the instant application is not the same as the original applications on which priority is being based. Applicant is asked to tell the relationship that is being claimed between the prior applications and the present application. Until this is cleared up the only date that will be given a priority date is that of 60/191,046 of 3/21/2000. The examiner notes that in the palm data of the USPTO there is no mention of a relationship between either 09/370,046 or 09/079,213 and WO 98/51662. Please clarify for the record if there is a relationship and what if any that relationship may be. According to palm data of the USPTO there is no relationship.

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The examiner notes that on the PTO 1449 applicant cites Ser No. 10/060734 which is now allowable and unavailable for review by the examiner since it is out for initial data capture. The class and subclass are carboxylic, phosphorus and sulfur acids. At the present time these are not being examined. However if the allowed claims are pertinent to the selected group. Applicant is requested to send them for double patenting review. There is also the same problem for US 10/115, 206. This reference does have a PG pub and the claims are drawn to a Z group that is a sugar and is non elected in this application. This is also the same problem for US Ser. No. 10/114,346 and Ser. No. 10/114351 which is also classified as allowed. However there is a prepub articles and as such the examiner will assume the allowed claims are the same and therefore there is an obvious type double patenting over the elected species and claim 1 of the allowed file US Ser No. 10/114,346 and an obvious type double patenting over claim 1 of 10/114,351.

Claim Rejections - 35 U.S.C. § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

351(a).

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4. Claims 1, 2, 6, 14, 15, 28, 72, 73, 74, 75, and 76 are rejected under 35 U.S.C. 102(b) as being anticipated by Somers (WO 9851662).

When Somers teaches 6-O-[4-[[1-[[3,5-bis(1,1-dimethylethyl)-4-hydroxyphenyl]thiol]-1-methylethyl]thio]-2,6-bis (1,1-dimethylethyl)phenyl]-Glucitol and a pharmaceutical composition thereof the claims are fully anticipated (see abstract attached to patent, claims 10-12 and specification pages 24-29 and example 58).

The examiner notes that this is the earliest report of this species.

Double Patenting

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground

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provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 1, 2, 6, 14,15,28, 72, 73, 74, 75, and 76 to the extent that they read on the species are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of copending Application No.10/ 114345.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the species being claimed in the instant invention has one less CHOH. However the method of action is the same and it would be obvious to one of ordinary skill in the art to have added another CHOH since the prior art has 5 and the instant invention has 4. The activity has not changed as an inhibitor of Vcam1 and the addition of another CHOH or a deletion of a CHOH would be an obvious variant to obtain another compound that would be similarly active since they are homologues and homologues are known to have similar activity chemically and physically. This rejection is written toward the elected species. However the boarder genus and exemplifications of the homologues would be referred to in a rejection over the genus of polyhydroxys being claimed if they were being examined at this point. However at this point the elected species has been found and so the rejection is drawn solely to that species.

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This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

7. Claims 1, 2, 6, 14, 15, 28, 72, 73, 74, 75, and 76 to the extent that they read on the species are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 10/114,351.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the species being claimed in the instant invention has one more CHOH. However the method of action is the same and it would be obvious to one of ordinary skill in the art to have removed one CHOH since the prior art has 3 and the instant invention has 4. The activity has not changed as an inhibitor of Vcam1 and the addition of another CHOH or a deletion of a CHOH would be an obvious variant to obtain another compound that would be similarly active since they are homologues and homologues are known to have similar activity chemically and physically. This rejection is written toward the elected species. However the boarder genus and exemplifications of the homologues would be referred to in a rejection over the genus of polyhydroxys being claimed if they were being examined at this point. However at this point the elected species has been found and so the rejection is drawn solely to that species.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

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Conclusion

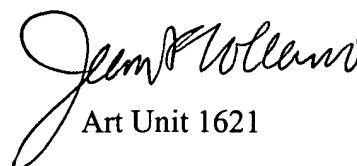
8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 4,734,527, US 3,897,500, US 3,576,883, US 3,704,327 and US 3,485,843 teach variations of the bis thio ether starting material and piperazine complex and the utilities of the compounds.
9. The file indicates two PTO 1449s were submitted the examiner can only find one in the application. The dates are 12/04/01 and 12/02/02. The examiner has the one filed 12/02/2002 Please send in the other if it exists. It may be a clerical error. Please clarify.
10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr J F Vollano whose telephone number is (703) 305-4483. The examiner can normally be reached on Monday to Thursday from 6:30 to 5:00 .
11. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter , can be reached on (703)308-4532 . The official fax phone number for the organization where this application or proceeding is assigned is (703)308-4556. It should be noted that the examiner cannot immediately work on a fax sent to this number.

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12. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-1235.

Jean F. Vollano

Primary Examiner

A handwritten signature in black ink, appearing to read "Jean F. Vollano", written in a cursive style.

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May 26, 2003